

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

FILED

FEB - 5 2010

CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY _____ DEPUTY CLERK

KINETIC CONCEPTS, INC.,
KCI LICENSING, INC., KCI USA, INC.
and WAKE FOREST UNIVERSITY
HEALTH SCIENCES

Plaintiffs,

VS.

BLUESKY MEDICAL CORPORATION
and SMITH & NEPHEW, INC.

Defendants.

NO. SA-08-CV-00102-WRF

JOINT PRETRIAL ORDER

Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., KCI Medical Resources, Medical Holdings Limited, KCI Manufacturing (collectively “KCI”) and Wake Forest University Health Sciences (“Wake Forest”)¹, together with Defendant Smith & Nephew, Inc. (“Smith & Nephew”) submit this Joint Pretrial Order pursuant to Local Rule CV-16, Rule 16 of the Federal Rules of Civil Procedure and this Court’s Third Amended Docket Control Order (Docket No. 279).

(1) QUESTIONS FOR THE COURT TO ASK PROSPECTIVE JURORS

The parties request that the Court ask the following questions of the jury panel:

¹ With respect to each of the named plaintiffs, Smith & Nephew contends that each Plaintiff must show that, since the time the Complaint was filed, it has had either legal title to the ‘081 and ‘651 patents or an exclusive license under those patents in order to have standing in this case and to invoke the jurisdiction of the Court over those patents. Having already met and conferred with Plaintiffs’ counsel, Smith & Nephew will promptly file a motion to dismiss each of the entities who cannot sustain their burden in proving standing.

1. Is there anyone here who has ever worked for, or has an immediate family member who has worked for Kinetic Concepts, Smith & Nephew, Wake Forest University, BlueSky Medical, Medela, Convatec, Innovative Therapies Inc., Apria, Universal Health Services (UHS), or Pressure Management Resources?
2. Do you have any beliefs or attitudes about Kinetic Concepts that would prevent you from being a fair and impartial juror in this case?
3. Do you have any beliefs or attitudes about Wake Forest University or Wake Forest University Health Sciences that would prevent you from being a fair and impartial juror in this case?
4. Do you have any beliefs or attitudes about Smith & Nephew that would prevent you from being a fair and impartial juror in this case?

(2) STATEMENT OF CLAIMS OR DEFENSES TO BE READ TO POTENTIAL JURORS

a. Plaintiffs²

Plaintiff Wake Forest University Health Sciences owns patents on wound treatment technologies. Plaintiff KCI is a medical technology company which makes and sells products for wound prevention and treatment throughout the United States. Wake Forest has granted KCI an exclusive license to its wound treatment patents, and under that agreement, KCI manufactures, markets and distributes a wound treatment product called the "V.A.C.," which stands for "Vacuum Assisted Closure" System.

Wake Forest and KCI contend that Defendant Smith & Nephew is infringing the Wake Forest patents by making, using, selling and offering to sell certain wound treatment products relating to negative pressure wound therapy, and they are seeking damages. Wake Forest and KCI maintain that the Wake Forest patents are valid because the inventions were not obvious at the time the patents were filed based on many considerations, including the initial skepticism,

² Smith & Nephew maintains that Plaintiffs' statement cannot be read to the jury until the Court first resolves the issues as to which plaintiffs, if any, have standing to maintain this action, and who actually possesses the exclusive license under the '081 and '651 patents. Plaintiffs disagree.

unexpected results, praise and recognition received by the invention, and the fact that it has been copied by Smith & Nephew.³

b. Defendant

Defendant Smith & Nephew markets and sells a variety of wound care products throughout the United States, including products relating to negative pressure wound therapy. Smith & Nephew maintains that it is entitled to sell its negative pressure products because those products do not infringe any of the patent claims at issue in this case.

In addition, Smith & Nephew maintains that the patent claims KCI is asserting are invalid for two separate reasons. First, the claimed subject matter would have been obvious to one of ordinary skill in the art, at the time the patents were filed, in violation of the patent law. Second, the claimed subject matter of some of the patent claims at issue is not adequately supported by the written description in the specifications of the patents, in violation of the patent law.

Because Smith & Nephew contends that the patent claims at issue have not been infringed and are invalid, Smith & Nephew maintains that any harm Wake Forest and KCI may have suffered from the presence of Smith & Nephew's products in the marketplace is unrelated to KCI's allegations of patent infringement and therefore Smith & Nephew owes no damages.

(3) PROPOSED STIPULATED FACTS

The following is a list of uncontested facts and stipulations entered into by the parties:

1. United States Patent No. 5,645,081 (the "'081 Patent") was issued on July 8, 1997.

³ Smith & Nephew objects to the inclusion of the argumentative portion of the above-noted sentence: "based on many considerations, including the initial skepticism, unexpected results, praise and recognition received by the invention, and the fact that it has been copied by Smith & Nephew." Plaintiffs contend that the language in question is no more argumentative than the statements in Smith & Nephew's proposed Statement of Claims and Defenses.

2. United States Patent No. 7,216,651 (the "651 Patent") was issued on May 15, 2007.
3. Wake Forest owns the '081 Patent and the '651 Patent ("Wake Forest patents").
4. Smith & Nephew purchased BlueSky as a wholly owned subsidiary on May 10, 2007.
5. Wake Forest, Kinetic Concepts Inc., KCI Licensing, Inc. and KCI USA, Inc. sued Smith & Nephew and Blue Sky on May 15, 2007 for patent infringement of the '651 Patent for the manufacture and sale of gauze-based negative pressure wound therapy products.
6. On December 11, 2008, Smith & Nephew publicly announced its intended launch of foam-based negative pressure wound therapy products.
7. On December 11, 2008, Wake Forest and KCI sued only Smith & Nephew for infringement of the '081 Patent for the manufacture and sale of its foam-based negative pressure products.
8. In the same December 11, 2008 suit, Wake Forest and KCI alleged that Smith & Nephew's manufacture and sale of its foam-based negative pressure products infringed the '651 Patent as well.
9. Plaintiff Kinetic Concepts, Inc. is a corporation organized under the laws of the State of Texas, having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230.
10. Plaintiff KCI USA, Inc. is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230.

11. Plaintiff KCI Licensing, Inc. is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230.

12. Plaintiff KCI Medical Resources is a company governed by the laws of Ireland having its principal place of business at Zephyr House, Mary Street, P.O. Box 709 GT, Grand Cayman, Cayman Islands.

13. Plaintiff Medical Holdings Limited is a company governed by the laws of Malta having its principal place of business at 171 Old Bakery Street, Valletta VLT 1455, Malta.

14. Plaintiff KCI Manufacturing is a company governed by the laws of Ireland having its principal place of business at 29/40 Upper Mount Street, Dublin 2, Ireland.

15. Plaintiff Wake Forest is a non-profit corporation organized under the laws of the State of North Carolina having its principal place of business at Medical Center Boulevard, Winston-Salem, North Carolina 27157-1023. Wake Forest is a wholly-controlled subsidiary of Wake Forest University.

16. Defendant Smith & Nephew, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 1450 Brooks Road, Memphis, Tennessee 38116.

(4) ISSUES TO BE TRIED BEFORE THE JURY

Plaintiffs will assert the following allegations:

- Direct, contributory, and induced infringement of Claims 2 and 5 of the '081 Patent by Smith & Nephew
- Contributory and induced infringement of Claims 42, 116/42, 121/42, 109/108/20, 116/20, 121/20 of the '651 Patent by Smith & Nephew

- Willful infringement (bifurcated for a possible second trial before the same jury)
- Damages, with the damages period to begin when Smith & Nephew began marketing or distributing its foam products

Smith & Nephew will assert the following affirmative defenses:

- Underlying facts regarding the invalidity of all of the asserted claims for obviousness under 35 U.S.C. § 103
- Possibly facts underlying that the two Bagautdinov articles are printed publications under 35 U.S.C. § 102(b)
- Invalidity of all of the pressure-range claims (*i.e.* Claims 2 and 5 of the '081 Patent and Claims 42, 116/42, and 121/42 of the '651 Patent) under 35 U.S.C. § 112

In support of its invalidity defenses, Smith & Nephew will rely upon no more than the following 20 references:

1. N.A. Bagautdinov, "Variant of External Vacuum Aspiration in the Treatment of Purulent Diseases of Soft Tissues," in Current Problems in Modern Clinical Surgery: Interdepartmental Collection, edited by V.Ye. Volkov (Chuvash State University, Cheboksary, U.S.S.R. 1986) pp. 94–96 (*Bagautdinov I*)
2. I. Capperauld and T.E. Bucknall, "Sutures and Dressings," in Wound Healing for Surgeons, edited by T.E. Bucknall and H. Ellis (Ballière Tindall, London 1984) pp. 75–93
3. M.E. Chariker, K.F. Jeter, T.E. Tintle, and J.E. Bottsford, "Effective Management of Incisional and Cutaneous Fistulae with Closed Suction Wound Drainage," Contemporary Surgery 34 (1989) 59–63
4. International Publication No. WO 90/11795 to Zamierowski
5. M.F. Fay, "Drainage Systems: Their Role in Wound Healing," AORN Journal 46 (1987) 442–456

6. K.F. Jeter, T.E. Tintle, and M. Chariker, "Managing Draining Wounds and Fistulae: New and Established Methods," in *Chronic Wound Care*, edited by D. Krasner (Health Management Publications, Inc., King of Prussia, PA 1990) pp. 240–246
7. F.E. Johnson, "An Improved Technique for Skin Graft Placement Using a Suction Drain," *Surgery, Gynecology, and Obstetrics* 159 (1984) 584–585
8. V.A. Kuznetsov & N.A. Bagautdinov, "Vacuum and Vacuum-Sorption Treatment of Open Septic Wounds," in Second All-Union Conference "Wounds and Wound Infections" (Abstracts of Presentations), edited by B.M. Kostiuchenok et al. (Moscow, USSR 1986) (*Bagautdinov II*)
9. S.V. Lokhvitsky and A.A. Bilkevich, "External Vacuum-Aspiration in the Treatment of Purulent Diseases of the Soft-Tissues" *Khirurgiya* 4 (1984) 130–134
10. W. Meyer and V. Schmieden, *Bier's Hyperemic Treatment in Surgery, Medicine, and the Specialties: A Manual of Its Practical Application* (1908)
11. Public Use of Dr. Mark E. Chariker in 1989
12. Public Use of Dr. Katherine F. Jeter in 1985
13. M. Schein, R. Saadia, J.R. Jamieson, and G.A.G. Decker, "The 'Sandwich Technique' in the Management of the Open Abdomen," *British Journal of Surgery* 73 (1986) 369–370
14. V.A. Solovev, Dissertation Abstract, *Treatment and Prevention of Suture Failures After Gastric Resection* (S.M. Kirov Gorky State Medical Institute, Gorky, USSR 1988)
15. International Publication No. WO 94/20041 to Argenta
16. S. Thomas, "Semipermeable Film Dressings," in *Wound Management and Dressings* (The Pharmaceutical Press, London 1990) pp. 25–34
17. U.K. Patent Application No. 2,195,255 to Thorn
18. U.S. Patent No. 2,122,121 to Tillotson
19. Z.Y. Yorsh (Ersh), "The Application of Penopolyurethane for Clearing Purulent Cavities and Wounds," *Vestnik Khirurgii Imeni I.I. Grekova* 133 (1984) 134–135
20. G. Živadinović, V. Đukić, Ž. Maksimović, Đ. Radak, and P. Peška, "Vacuum Therapy in the Treatment of Peripheral Blood Vessels," *Timok Medical Journal* 11 (1986) 161–164

Plaintiffs challenge whether *Bagautdinov I* and *Bagautdinov II* are printed publications under 35 U.S.C. § 102(b).

(5) IDENTIFICATION OF EXHIBITS

The parties will submit a joint exhibit list to the Court, entitled Parties' Joint Trial Exhibit List. Plaintiffs will maintain the numbering system used on Plaintiffs' Trial Exhibit List and Rebuttal Trial Exhibit List, i.e., P-1, etc., where "P" stands for "parties." Defendant will renumber its exhibits using the same "P" prefix, beginning with P-1000, except that Defendant will remove any exhibits that are duplicative of exhibits already on Plaintiffs' list (and provide a cross-reference table for any such removed exhibits to Plaintiffs). Other than duplicates, no party will remove exhibits from the Parties' Joint Trial Exhibit List. That the parties are submitting a Joint Trial Exhibit List does not in any way preclude any party from maintaining their admissibility objections to a particular exhibit.

(6) IDENTIFICATION OF LIVE WITNESSES

Plaintiffs intend to call the following live witnesses at trial:

Louis Argenta, M.D.
Christopher Attinger, M.D.
Cathy Burzik
Michael DelVacchio
Teresa Johnson
Dennis Kimmage, Ph.D.
James Malackowski
Michael Morykwas, Ph.D.
James Leininger, M.D.
Dennis Orgill, M.D., Ph.D.
Joe Rodriguez
Dianne Rudolph, R.N.
Antoinette Tease
Boris Vinogradksy, M.D.

Smith & Nephew intends to call the following live witnesses at trial:

Nail Bagautdinov, M.D.
Robin Carlstein
David Cavanaugh
Mark Chariker, M.D.
Thomas Dugan
Ian Gordon, M.D.
Katherine Jeter, PhD
Bryan Medlock
Joel Petrow
Charlotte Rutherford
Michael Wagner

(7) IDENTIFICATION OF WITNESSES BY DEPOSITION

Plaintiffs intend to play the deposition testimony of the following witnesses at trial:

Edward Armstrong
Bill Caprio
Martin Connors
Simon Dawkins
David Hoffman
John Mallon
PMR, LLC
Richard Weston

Plaintiffs will also present video testimony from the following witnesses if they are removed from Smith & Nephew's live witness list:

Robin Carlstein
Tom Dugan
Joel Petrow

Smith & Nephew intends to play the deposition testimony of the following witnesses at trial:

Yuriy Grikhanov
LSU
Marie McGregor
Tess Tintle
David Zamierowski

Smith & Nephew will also present video testimony from the following witnesses if they are removed from Plaintiffs' live witness list:

Louis Argenta, M.D.
Catherine Burzik
Michael DelVacchio
Dennis Kimmage, PhD
Michael Morykwas, PhD
James Leininger, M.D.

(8) STATUS OF DISCOVERY

Plaintiffs have moved for exclusion of the testimony of some Defendant's witnesses on the basis that Plaintiffs have not been provided with sufficient discovery.

Plaintiffs will depose Dr. Mark Chariker on February 14, 2010 at 10:00 am in San Antonio. If Smith & Nephew decides to present the testimony of Bryan Medlock or David Cavanaugh, Plaintiffs will first be provided the opportunity to depose them.

(9) STIPULATION CONCERNING AUTHENTICITY

Any document produced by a party that on its face appears to have been authored by an employee, officer, or agent of that party shall be deemed authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary. Any document that on its face was authored or prepared by a third party that was produced in discovery by a party, if offered by the opposing party, shall be deemed authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary.

(10) FEDERAL JUDICIAL CENTER VIDEO

The parties agree to play the Federal Judicial Center video titled, "An Introduction to the Patent System." The parties request that the Court play the video prior to the Court's reading of the Preliminary Jury Instructions and counsels' presentation of Opening Statements.

(11) ORDER OF TRIAL PRESENTATION

Plaintiffs intend to offer all relevant testimony from witnesses presented during its case-in-chief, regardless of whether such testimony goes to an issue on which Plaintiffs bear the burden of proof (e.g. infringement) or an issue on which Defendant bears the burden of proof (e.g. invalidity).

Smith & Nephew requests that the Court order the parties to adhere to the order of proof when presenting their evidence. That is, Smith & Nephew requests that in Plaintiffs' case-in-chief, Plaintiffs submit evidence only on issues on which they bear the burden of proof (i.e., infringement, willfulness, and damages). Then Smith & Nephew would rebut Plaintiffs' infringement, willfulness, and damages evidence and submit evidence on issues on which Smith & Nephew bears the burden of proof (i.e., invalidity). The Court can then allow appropriate rebuttals by both parties, if necessary. Smith & Nephew further contends that if Plaintiffs are permitted to present all issues in their case-in-chief, then Plaintiffs should be precluded from presenting any rebuttal case.

(11) PENDING MOTIONS

Subject to the rulings made from the bench at the January 25, 2010 Pretrial Conference, to be confirmed by the transcript to be received January 29, 2010, the following Motions are pending before the Court:

- (1) Smith & Nephew's Motion to Preclude Boris Vinogradsky from Testifying as an Expert, in addition to testifying as a fact witness (Docket No. 323)
- (2) Smith & Nephew's Motion to Preclude Diane Rudolph from Testifying as an Expert, in addition to testifying as a fact witness (Docket No. 324)
- (3) Smith & Nephew's Motion to Exclude Dennis Kimmage as a Testifying Expert (Docket No. 327)
- (4) Plaintiffs' Amended Motion in Limine (Docket No. 379) and First Supplement to Amended Motion in Limine (Docket No. 380), including Plaintiffs' Motion in Limine (Docket Nos. 352, 353, 355 and 385)
- (5) Smith & Nephew's Motion to Strike Plaintiffs' Jury Demand on Questions of Law (Docket No. 373)

(12) DISMISSED CLAIMS

Plaintiffs dismiss without prejudice the following previously asserted claims:

1. Allegations of patent infringement of the following previously asserted claims:
 - Claims 1-4, 6-13, 15-30, 32-40, 43-50, 54-55, 57, 59, 61-62, 64-65, 69-71, 76-92, 95-97, 98/12, 100-102, 105-108, 111-115, 116/108, 117-120, 121/108, and 122-125 of the '651 Patent;
 - Claims 24, 29, 42, and 44 of the '046 Patent;
 - Claims 1, 3, and 4 of the '643 Patent; and
 - Claims 1, 11, 12, 27, and 30 of the '081 Patent.
2. Any allegations of infringement relating to Smith & Nephew's gauze-based products.
3. Any allegations of infringement under the doctrine of equivalents
4. Any allegations of direct infringement by Smith & Nephew of Claims 42, 116/42, 121/42, 109/108/20, 116/20, 121/20 of the '651 Patent
5. Any allegations of infringement by Defendant BlueSky, in view of the following stipulations:
 - a. BlueSky has not made, used, sold, rented, offered for sale or imported into the U.S. any negative pressure wound therapy products since December 11, 2008, nor has it induced anyone else to do so.
 - b. If any pumps manufactured by or for BlueSky have been used, sold, rented, or offered for sale in the U.S. in connection with any Smith & Nephew foam NPWT dressing kits since December 11, 2008, and if such acts are found to

constitute patent infringement, then Smith & Nephew agrees that it is liable for such acts.

Defendant dismisses without prejudice the following previously asserted claims:

1. Claims for a declaration of non-infringement and invalidity of the previously asserted claims identified in numbers 1 and 2 above.
2. Invalidity of patent claims based on anticipation.
3. Claims for a declaration of patent unenforceability of the '651 Patent due to inequitable conduct.

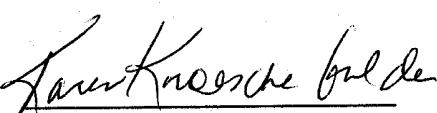
IT IS SO ORDERED.

SIGNED this 5th day of February, 2010.

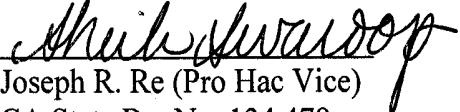

THE HONORABLE ROYAL FURGESON
UNITED STATES DISTRICT JUDGE

Approved as to form and content.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been sent via e-copy on the 22nd day of January, 2010 to:

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